K041717 JAN 13 2005

II. 510(k) SUMMARY

Submitted By:	A.P. Deauville, LLC. 594 Jersey Ave. New Brunswick, NJ 08901 (732) 545-0200
Contact Person:	Scott L. Baier
Date Prepared:	June 23, 2004
Proprietary Name:	Power Stick® Male Latex Condoms
Common Name:	Male Latex Condom
Classification Name:	Condom (21 CFR §884.5310)
Predicate Device:	Male Latex Lubricated Condom [510(k) Number K040185]

Description of the Device: This condom is made of a natural latex sheath, which completely covers the penis with a closely fitted membrane. These two types of condoms, ribbed and dotted-ribbed, are at a nominal length of 170mm., a nominal width of 52 mm (±2mm) and are at a nominal thickness of .06 mm (±.02 mm).

Intended Use of the Device: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Technological Characteristics: This design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex and has the same technological characteristics as the predicate condoms identified [510(k) Number K040185]. The condoms described in K040185 are manufactured ribbed and dotted/ribbed Natural Rubber Latex male condoms with a silicone lubricant. The condom design conforms to domestic and international regulations: ASTM D3942, ISO 4074 and EN 600. All physical testing and final release testing revealed in conformance with required specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Scott L. Baier
Operations Manager
A. P. Deauville, LLC
594 Jersey Avenue
NEW BRUNSWICK NJ 08901

Re: K041717
Trade/Device Name: Power Stick® Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: December 15, 2004
Received: December 27, 2004

Dear Mr. Baier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041717

Device Name: Power Stick Male Latex Condoms

Indications For Use: The Power Stick Male Latex Condom is used for contrceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Prescription Use _____ AND/OR Over-The-Counter Use XXX
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041717